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Next 1 Page(s) In Document Exempt

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**President's Commission for the Study of Ethical
Problems in Medicine and Biomedical and Behavioral Research**

Suite 555, 2000 K Street, N.W., Washington, DC 20006

The Honorable William J. Casey
Director
Central Intelligence Agency
Washington, D.C. 20505

Dear Mr. Casey:

In March 1980, pursuant to Section 1802(c) of the legislative mandate to this Commission (set forth in Title III of Public Law 95-622), I wrote to your predecessor requesting information regarding your agency's guidelines and regulations governing research with human subjects. Copies of that letter and your agency's response are enclosed. A draft summary of your policies and regulations, based upon your agency's response, is enclosed for your review prior to inclusion in our report to the Congress. Please let me know if the summary is accurate or, if not, what modifications should be made. If you have issued any policy statements or regulations on this topic subsequent to your last communication with this office, please so indicate and enclose copies with your response.

In addition to its responsibility to report to the Congress on the adequacy and uniformity of federal regulations for the protection of human subjects, this Commission is required to assess the adequacy of the implementation of such regulations, guidelines, policies, etc. To assist us in responding to this portion of the mandate, could you please provide a description of the following, to the extent applicable, and provide copies of relevant documents:

1. Policies or procedures (formal or informal) by which your agency evaluates or monitors the actual performance of agency or extramural Institutional Review Boards (e.g., reporting requirements, site visits, record reviews);
2. Standards and procedures to guide the investigation of complaints regarding the review or conduct of research involving human subjects;
3. The number and character of any such reports or complaints received in the last 5 years (FY 1976-1981); and
4. The manner in which these complaints were disposed of, the findings that were made, and the sanctions, if any, that were imposed.

W.J. Casey
Page 2

We would appreciate receiving your response by August 1, 1981, so that the staff can prepare a summary and analysis of the response of all federal agencies and the Commission, in turn, can formulate any recommendations it may wish to include in its Biennial Report to the Congress, due December 31, 1981. I will be happy to answer any questions you or your staff may have regarding the preparation of your response. Please feel free to call me at 653-8051 if I can be of assistance. Thank you for your cooperation.

Sincerely yours,

Barbara Mishkin

Barbara Mishkin
Deputy Director

Enclosures

cc:

Liaison Officer

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